

## **REMARKS**

The outstanding Office Action of January 12, 2007 rejects Claim 15 under 35 U.S.C. 101 as failing to have a concrete result and 35 U.S.C. 103(a) over Crutchfield. The application has been amended in response to the Examiner's comments and is now believed to be in condition for allowance.

**Attached is a complete listing of all claims in ascending numerical order. Each claim has been provided with the proper status identifier.**

Specifically, newly submitted independent Claim 16, Claim 15 in rewritten form, defines a classification and management system for patients with lower extremity arterial occlusive disease by examining, collecting and recording data of a patient with lower extremity arterial occlusion disease, including pertinent physical findings and noninvasive arterial pressure and blood flow data, comparing the patient data against a medically accepted set of disease specific criteria to provide an initial diagnosis and preliminary classification of those patients "potentially at risk" and those patients "not at risk" of developing complications of arterial occlusive disease, referring those patients classified as "potentially at risk" of arterial occlusive disease to an accredited laboratory for noninvasive vascular evaluation, classifying each patient against medically accepted criteria as "at risk" or "not at risk", recording the "at risk" or "not at risk" patient final classification, referring patients having a final classification of "at risk" for critical ischemia with associated extremity lesions and patients with noninvasive evidence of

severe ischemia to a vascular surgery facility for vascular surgical assessment to determine whether revascularization is necessary, assessing such “at risk” patients against medically accepted criteria as “clinical indication for operation” or “no indication for operation” at the vascular surgery facility, transmitting patient assessments assessed as “clinical indication for operation” or “no indication for operation” assessment to the evaluating authority, informing those patients assessed as “clinical indication for operation”, electing either revascularization and periodic management system evaluation at the healthcare facility or routine wound care and periodic reevaluation at the healthcare facility by patients assessed as “clinical indication for operation”, monitoring patients assessed as “no indication for operation” by the healthcare facility with increased precautions to monitor for detection of any deterioration that would require reassessment, referring patients having ulcers, pain or gangrene at the time of “no indication for operation” assessment for reassessment, recording the reasons for not referring such patients as “clinical indication for operation”, referring patients classified as “no indication for operation” that develop ulcers, pain and/or gangrene to the vascular surgery facility for reassessment, reassessing the referred patient at the vascular surgery facility against medically accepted criteria as “no indication for operation” or “clinical indication for operation”, transmitting the reassessment of “no indication for operation” or “clinical indication for operation” to the evaluating authority for reevaluation as “no indication for operation” or “clinical indication for operation”, transmitting the reevaluation to the healthcare facility with the appropriate medical procedure and regimen, treating and monitoring patients classified

as “not at risk”, “at risk” and assessed as “no indication for operation” or “clinical indication for operation” at the healthcare facility, providing “not at risk” patients without limb ulcers routine care and precautions at the healthcare facility, providing “not at risk” patients with limb ulcers routine wound care at the healthcare facility, providing “not at risk” patients with limb ulcers periodic reevaluation by the evaluating authority, providing “at risk” patients assessed as “no indication for operation” or “operation not elected by patient”, and “clinical indication for operation” patient undergoing revascularization at the vascular surgery facility with intensive wound care at the healthcare facility, and, providing periodic reevaluations of “at risk” patients assessed as “no indication for operation” or “operation not elected by patient” with increased precautions at the healthcare facility.

The system classifies patients with lower extremity arterial occlusive disease by observing arterial pressure and blood flow data, lesions, ischemia, measured against accepted medical practices and procedures to establish the appropriate treatment required. This claim structure is not unlike the claim structure of Crutchfield as relating to the applications of Section 101.

Regarding Section 103, Crutchfield relates to a system and method for physicians to evaluate individuals for vascular health and to detect any deviations from vascular health by evaluating specific parameters of vascular function during routine physical examinations and to evaluate individuals with the risk factors for cerebral vascular malfunction. A patient population of individuals at high risk of stroke may be evaluated systematically over time to determine whether ongoing vascular changes may

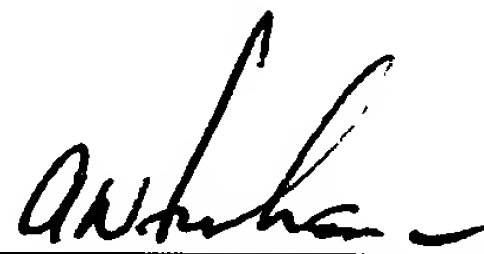
indicate an incipient cerebral vascular event, such as stroke. In this manner, it may be possible to predict the occurrence of a first stroke, thereby preventing the stroke. The system can also provide a mechanism for monitoring individuals who have experienced a stroke. The system provides a system and method for performing non-invasive clinical research studies to evaluate potential vascular effects of substances or combinations of substances at selected dosages and in selected patient populations.

Crutchfield does not teach or suggest a system of evaluating, classifying and selectively treating patients with lower extremity arterial occlusive disease with alternative regimes dictated by observable patient conditions.

In view of the amendments contained herein and the discussion in support thereof, allowance of this application is respectfully requested.

Notwithstanding, in the event that this response does not completely and fully address the matters and issues set forth in the outstanding Office Action, Examiner Rines is invited to contact Applicant's attorney by telephone in order to expeditiously conclude this prosecution.

Respectfully submitted,



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